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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,655	08/03/2001	Michael H. Cardone	M00925/70106	5833

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,655	CARDONE ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,73 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,73 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 1/24/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 11-72 are cancelled.
2. Claim 1 is amended.
3. Currently, claims 1-10, 73-74 are under examination.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claim 1, 3, 4, 6, 7, 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al. (US 6475808).

Wagner et al teach a protein array for in vitro screening biomolecular activities. Wagner et al teach covalently immobilizing proteins to the solid support of the array, i.e. organic thinfilm (Col. 7, line 35-45). The covalent immobilization include, maleimide, N-hydroxysuccinimide conjugation on the solid substrate (Col. 16, line 60-67). The solid support materials can be of glass (Col. 7, line 8-12). Wagner et al also teach an antibody array with antibody fragments against known antigens (Col. 25, line 22-28). Examiner takes the position to interpret the claim broadly because applicant further limits the "linker molecule" with merely functional moieties, such as maleimide, vinyl sulfonate or hydroxy succinimide groups. Examiner considers that the covalent binding in Wagner et al reference is a linker molecule itself with various functional moieties.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 2, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Sakata et al. (EP 0140489) and Bagchi et al.. (US 4855219)

Wagner et al reference has been discussed but does not explicitly teach covalently binding linker such as vinyl sufone, carboxy groups. Sakata et al. teach using covalent modification for increasing immunodetection, including adding hydroxyl, carboxyl, succinimide or sulfhydryl groups. (page 5, line 18-22; 6, line 5 to page 7, line 1-15) Similarly, Bagchi et al. also teach using compounds containing vinyl slufone groups for cross-linking purposes on the solid support, i.e. microplate (Col. 3, line 12-18) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Wagner et al with the methods of covalent immobilization method for attachment of the protein or antibody in the microarray as taught by Sakata and Bagchi et al because covalent modifications on a solid phase in

increasing sensitivity of immunoassay is well-known in the art and different compounds used for covalent modifications on the solid support have been developed in the fields, such as adding the vinyl sufone, carboxy, N-hydroxy succinimide groups.

5. Claims 9-10 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al in view of MacBeath et al. (J. Am. Chem. Soc. 1999 121: 7967-7968)

Wagner et al reference has been discussed but does not explicitly teach microarray and the density of the microplates for screening samples. MacBeath et al. teach a microarray having microwell density of 2000 spots per cm^2 for mass screening purposes (See Figure 4) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Wagner et al with the microarray having a high density as taught by MacBeath et al since the mass screening is the ultimate purpose in microarray and arrangement of density for array more samples involves only skill in the art.

Response to Applicant's Arguments

6. The rejections of claims 1, 3, 4, 6, 7 and 8 under 35 USC §102(e) as being anticipated by Wagner et al. are maintained.

Applicant argues that Wagner et al. do not disclose or suggestion of a protein or protein fragment having a terminus forming a covalent bond with a linker molecule. Applicant argues that Wagner et al. only disclose that protein can be covalently immobilized to a substrate, and does not indicate that the terminus of the protein is involved with the covalent immobilization.

Applicant's arguments have been considered but are not persuasive. Examiner had pointed out that the covalent immobilization taught by Wagner et al. includes, maleimide,

N-hydroxysuccinimide conjugation on the solid substrate (Col. 16, line 60-67). Although Wagner et al. do not explicitly teach that such chemical modification would result in forming a terminus covalent bound to the linker, it is nevertheless an inherent characteristic for using the maleimide or N-hydroxysuccinimide interaction with the protein of interest. Applicant also indicates that proteins containing a cysteine residue may form a covalent bond with an electrophilic linker such as the *maleimide group* at the terminus of the protein (See Section 0062; Section 0065)(emphasis added). Accordingly, when one ordinary skill following the teaching of Wagner et al. using the maleimide linker modification to the proteins, it would inherently forming covalent bond to the terminus of the proteins.

7. The rejections of claims 9, 10, 73-74 under 35 USC §103(a) as unpatentable over Wagner et al. in view of MacBeath et al. are maintained.

Applicant argues that the "MacBeath does not appear to have been publicly available more than one year prior to the earliest date to which the rejected claims may be entitled to the benefit of priority (i.e. August 3, 2000), and, therefore, do not concede that MacBeath is prior art to the claimed invention" (See Remark, page 3, fourth paragraph).

Applicant's argument has been considered but is not persuasive. The date of the MacBeath is in the year of 1999, whereas the priority claimed by applicant is 8/3/2000. Under 35 USC §103(a), there is *no requirement* limited to a reference "more than a year" before the priority date of the application. Rather, any reference, as long as available prior to the priority date within section of 102(a) and 102(b) of 35 USC, could be a proper reference (See 35 USC §103(a)). Therefore, the rejection is deemed proper.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Jacob Cheu
Examiner
Art Unit 1641

March 11, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/17/05